

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF GEORGIA  
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004
		4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
		Case No.
LIABILITY LITIGATION	*	4:12-cv-250 (Nielsen)

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O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiff Susan Nielsen was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Nielsen brought this product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Nielsen also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Mentor seeks summary judgment on several of Nielsen's claims. For the reasons set forth below, Mentor's partial summary judgment motion (ECF No. 41 in 4:12-cv-250) is granted in part and denied in part.

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R.

Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

#### FACTUAL BACKGROUND

Viewed in the light most favorable to Nielsen, the record reveals the following.

Dr. Maurice Bouchard implanted Nielsen with ObTape on November 22, 2004. Nielsen did not see any materials from Mentor regarding ObTape, and she did not speak with any representatives of Mentor about the product. Nielsen asserts that she suffered various injuries caused by her ObTape.

Nielsen contends that Mentor misrepresented to Dr. Bouchard (or concealed from him) an accurate complication rate for ObTape, the severity of known ObTape complications, and true information about ObTape's physical characteristics. *E.g.*, Bouchard Dep. 27:22-28:11, 70:9-20, ECF No. 43-3. She also pointed to evidence that if Dr. Bouchard had known the true risks of ObTape, he would not have implanted it in Nielsen. *Id.*

at 73:18-74:5. And she pointed to evidence that she relied on her doctors' judgment in deciding to proceed with the ObTape implant. Nielsen Dep. 107:8-23, ECF No. 43-3.

Nielsen is a Florida resident whose ObTape-related treatment took place in Florida. Nielsen filed her Complaint on September 20, 2012. She asserts claims for personal injury under the following theories: negligence, strict liability design defect, strict liability manufacturing defect, strict liability failure to warn, breach of implied warranties, breach of express warranties, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation.

#### DISCUSSION

Nielsen filed her action in this Court under the Court's direct filing order. The parties agreed that for direct-filed cases, the "Court will apply the choice of law rules of the state where the plaintiff resides at the time of the filing of the complaint." Order Regarding Direct Filing § II(E), ECF No. 446 in 4:08-md-2004. Nielsen is a Florida resident whose ObTape-related treatment took place in Florida, and the parties agree that Florida law applies to her claims.

Mentor seeks summary judgment on Nielsen's claims for breach of warranty, misrepresentation, and fraudulent concealment. Nielsen does not contest summary judgment on her breach of warranty claims, so Mentor is entitled to summary

judgment on those claims. The Court addresses the remaining claims in turn.

### **I. Fraudulent and Negligent Misrepresentation Claims**

Mentor seeks summary judgment on Nielsen's fraudulent and negligent misrepresentation claims, contending that Florida law requires Nielsen to prove that she was injured because *she* relied on a misrepresentation from Mentor. But under Florida law, a manufacturer generally has a duty to warn a physician—not the patient—of a medical device's risks. *E.g., Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989). And a misrepresentation claim in a medical device case can be premised on the manufacturer's alleged misrepresentations to a physician. *E.g., Baker v. Danek Med.*, 35 F. Supp. 2d 875, 878 (N.D. Fla. 1998) (finding that negligent misrepresentation claim failed because the *patient's doctor* did not rely on any representations from bone screw manufacturer in deciding to use them in the patient). Thus, if a plaintiff can establish that the manufacturer made misrepresentations to her physician regarding the risks of a product and that the physician would not have recommended the product for the plaintiff had he known the product's true risks, then the reliance and causation elements are satisfied.

Here, Nielsen asserts that Mentor, intending to defraud her and induce her to undergo the ObTape procedure, made

misrepresentations to Dr. Bouchard about the safety of ObTape that induced him to recommend ObTape to her. Nielsen further contends that she relied on Dr. Bouchard in deciding to proceed with the ObTape procedure. And Nielsen produced evidence that Dr. Bouchard would not have implanted her with ObTape had he known its true risks. Thus, the Court is satisfied that a genuine fact dispute exists on the justifiable reliance and causation elements, and Mentor is not entitled to summary judgment on Nielsen's fraud and misrepresentation claims.

## **II. Fraudulent Concealment Claim**

Mentor also seeks summary judgment on Nielsen's fraudulent concealment claim. In support of this argument, Mentor points to *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp. 2d 1064, 1073 (S.D. Fla. 2003), which states that "[a]llegations of fraudulent concealment by silence must be accompanied by allegations of a special relationship that gives rise to a duty to speak." In that case, individuals provided tissue samples to researchers who were trying to determine the gene responsible for a disease; once the researchers isolated the gene, they obtained a patent that restricted certain testing and research on the gene and its mutations. The donors sued, contending that the researchers fraudulently concealed that they would patent their discovery and license testing under the patent. The court, however, found no fiduciary relationship

between the donors and the researchers and thus concluded that there was no duty of disclosure to the plaintiffs. *Id.*

But *Greenberg* does not apply here. Mentor cannot seriously dispute that it had a duty to disclose the true risks of ObTape to physicians like Dr. Bouchard. Moreover, Florida courts have recognized fraud claims based on a manufacturer's omission of material facts about a medical device. *Adams v. G.D. Searle & Co.*, 576 So.2d 728, 730 (Fla. Dist. Ct. App. 1991) (reversing dismissal of fraud claim because the plaintiff alleged that the defendant, intending to induce a doctor to prescribe its product to the plaintiff, failed to disclose material facts about its product to the plaintiff's doctor). Nielsen presented sufficient evidence that Mentor concealed material facts about the risks of ObTape to Dr. Bouchard and that Dr. Bouchard relied on those omissions to Nielsen's detriment. Accordingly, the Court denies summary judgment as to her fraudulent concealment claim.

#### CONCLUSION

As discussed above, Mentor's partial summary judgment motion (ECF No. 41 in 4:12-cv-250) is granted as to Nielsen's breach of warranty claims but denied as to her misrepresentation and fraudulent concealment claims.

Within seven days of the date of this Order, the parties shall notify the Court whether the parties agree to a *Lexecon* waiver.

IT IS SO ORDERED, this 14th day of December, 2015.

s/Clay D. Land

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CLAY D. LAND

CHIEF U.S. DISTRICT COURT JUDGE  
MIDDLE DISTRICT OF GEORGIA